



U.S. Department  
of Transportation

400 Seventh Street, S.W.  
Washington, D.C. 20590

**Pipeline and Hazardous  
Materials Safety  
Administration**

**JUN 17 2005**

DOT-E 13422

EXPIRATION DATE: May 31, 2007

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Puritan Bennett  
Plainfield, IN

2. PURPOSE AND LIMITATION:

a. This exemption authorizes the transportation in commerce of a non-DOT specification cylinder that is a component of a portable medical unit containing oxygen, refrigerated liquid (portable unit) and authorizes use of such portable units on board passenger-carrying aircraft. This exemption provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. Nothing in is this exemption waives or supersedes any requirement or prohibition by an airline, or other governmental agency regarding transportation of the portable unit on a passenger-carrying aircraft.

b. The safety analyses performed in development of this exemption only considered the hazards and risks associated with transportation in commerce.

c. Nothing in is this exemption supersedes any requirement of another federal agency to obtain an approval, waiver, or other authorization for use of the HELiOS portable device. Operating requirements of the Federal Aviation Administration (14 CFR 121.574(a)(1)(iii)) stipulate that equipment for the storage, generation, or dispensing of oxygen must be maintained by the relevant air carrier's (certificate holder) approved maintenance program. Persons using this exemption should consult their air carrier to determine if this device is authorized for use by passengers.

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3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 172.101(9A) in that carriage of oxygen, refrigerated liquid is forbidden on passenger-carrying aircraft; and §§ 173.316 and 175.3 in that the transport of a non-DOT specification cylinder is not authorized except as specified herein.
5. BASIS: This exemption is based on the January 16, 2004 application of Puritan Bennett, and additional information dated April 26, May 14, June 16, August 24 and August 30, 2004 submitted in accordance with § 107.105 and the public proceeding thereon.
6. HAZARDOUS MATERIALS (49 CFR § 172.101):

| Hazardous Materials Description                |                        |                       |               |
|--|------------------------|-----------------------|---------------|
| Proper Shipping Name                           | Hazard Class/ Division | Identification Number | Packing Group |
| Oxygen, refrigerated liquid (cryogenic liquid) | 2.2                    | UN1073                | N/A           |

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Packaging prescribed is a non-DOT specification insulated cylinder that is a component of the Puritan Bennett HELiOS PPM-1 (Models H-300 and H-300 Plus) liquid oxygen system. The liquid oxygen system must meet the requirements of the Mallinckrodt Verification Test Summary Report for PPM-1 HELiOS Small Portable unit dated 1/19/00 and Puritan Bennett Validation Test Summary Report for HELiOS H-300 Portable dated 4/15/01 on file with the Office of Hazardous Materials Exemptions and Approvals (OHMEA). The non-DOT specification cylinder must conform with the DOT 4L Specification (§§ 178.35 and 178.57) except as follows:

§ 178.57 (a) Type, size, service pressure and design service temperature.

- (1) Type and size. Must be fusion welded. Water capacity may not exceed one pound.
- (2) Service pressure. May not exceed 22 psig.

- (3) Design service temperature. Must be -320°F or colder.

§ 178.57(d) Manufacture.

\* \* \* \* \*

- (2) \* \* \* The heads of the cylinder must be torispherical.

- (3) \* \* \* except the sixth sentence is deleted and the fifth sentence is replaced with the following:

"The construction must be such that the total heat transfer from the atmosphere at ambient temperature to the cylinder lading may not exceed 0.200 Btu per hour per °F temperature differential per pound of water capacity of the cylinder, but not to exceed 2.0 pounds of evaporated oxygen, refrigerated liquid oxygen per day.

§ 178.57(h) Openings in Cylinder.

- (1) \* \* \* except a 3/16" diameter tube is authorized to be fusion welded or brazed directly to each head. Brazing must be in accordance with Puritan Bennett procedure: Manual Brazing SPI 294 on file with the OHMEA.

§ 178.57(p) Marking.

Applies, except that the outside of each portable unit must be marked "DOT-E 13422" in letters at least 0.25 inch high on a contrasting background.

b. TESTING -

- (1) Puritan Bennett must certify each portable unit authorized by this exemption. Each portable unit must be leak tested at test pressure and visually inspected in accordance with the requirements of Puritan Bennett document H-300 Service Repair, Stations 1 through 6 on file with the OHMEA.

- (i) The inspection must be: documented on a Service Repair Form maintained by Puritan Bennett; and available to a DOT representative upon request.

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(ii) A certification decal must be placed on the outside of each portable unit which will be used on a passenger-carrying aircraft. The decal must include as a minimum, the serial number of the unit and the expiration date of the certification. The expiration date may not exceed 90 days from the date the inspection is performed.

(2) Any portable unit determined to be leaking or damaged must be repaired and successfully leak tested before being returned to service.

c. OPERATIONAL CONTROLS - Puritan Bennett must provide instruction in the proper use of the portable unit and a written copy of the manufacturer's instructions to each patient on the proper use of the portable unit on a passenger-carrying aircraft. Prior to use of this exemption, a current copy of the manufacturer's instructions must be on file with OHMEA. At a minimum, the following information must be included in the instructions:

- (1) The exemption number.
- (2) Methods to prevent the accumulation of oxygen in the cabin, such as by turning off the oxygen supply valve when the portable unit is not being used.
- (3) A warning against carrying the portable unit under a coat or any form of clothing and a statement that the portable unit must be visible at all times.
- (4) A warning to keep all flammable materials away from the portable unit.
- (5) A warning to keep all portable units out of the reach of children.
- (6) A warning that no unauthorized individuals shall be allowed to tamper with the portable unit.
- (7) A warning to keep oils, greases, Vaseline, lotions, facial creams, and hair dressings away from the systems. Aerosol sprays are also prohibited from use in the vicinity of the systems.
- (8) Notification that only one portable unit may be transported by a passenger on a passenger-carrying aircraft.

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(9) A notification that the portable unit may not be refilled during transportation.

(10) Instructions on the necessary safeguards and proper procedures to be followed in the event of fire or accident involving the portable unit.

8. SPECIAL PROVISIONS:

a. A person who is not a holder of this exemption who receives a package covered by this exemption may reoffer it for transportation provided no modification or change is made to the package or its contents and it is reoffered for transportation in conformance with this exemption and the HMR.

b. A current copy of this exemption and the manufacturer's instructions must be maintained at each manufacturer and distributor facility where the portable unit is offered or reoffered for transportation or provided to patients.

c. Airline personnel must be provided instructions on the necessary safeguards and proper procedures to be followed in the event of fire or accident involving the portable unit.

d. Each passenger may carry only one portable unit aboard passenger-carrying aircraft. Additional portable units or replacement units are not authorized. The portable unit may only be used by a passenger in need of oxygen, provided the passenger has, in their immediate possession, a current copy of manufacturer's instructions (see paragraph 8.h.) for portable unit and is knowledgeable in the proper use of the portable unit.

e. A portable unit may not be placed in an overhead compartment of a passenger-carrying aircraft cabin or in a checked baggage compartment.

f. A portable unit used under this exemption may not have any outstanding recall notices.

g. In addition to the above, the following provisions apply. The requirement for a doctor's documentation of proof for need for medical oxygen by a passenger may be required by the airline at their discretion. Airlines must be notified in advance of the intent to bring the portable unit on a passenger aircraft.

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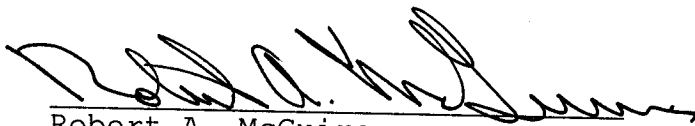
- h. A portable unit may not be offered or transported on a passenger-carrying aircraft after the expiration date indicated on the manufacturer's certificate on the portable unit.
- i. Nothing in this exemption waives or supersedes any requirement or prohibition by an airline, or other governmental agency regarding transportation of the portable unit on a passenger-carrying aircraft.
9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle and passenger-carrying aircraft.
10. MODAL REQUIREMENTS:
- a. A current copy of this exemption must be carried aboard each aircraft or motor vehicle used to transport packages covered by this exemption. Puritan Bennett may provide the air carrier a current copy of the exemption or the air carrier may obtain a current copy of the exemption at <http://hazmat.dot.gov/exemptions>.
- b. Drivers must have been instructed as to necessary safeguards and proper procedures in the event of unusual delay, fire, or accident.
11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this exemption and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:
- o All terms and conditions prescribed in this exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
- o Persons operating under the terms of this exemption must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this exemption, including display of its number, when this exemption has expired or is otherwise no longer in effect.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this exemption are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this exemption must notify the Associate Administrator for Hazardous Materials Safety -- OHMEA, in writing, of any incident involving a package, shipment or operation conducted under terms of this exemption.

Issued in Washington, D.C.:



Robert A. McGuire  
Associate Administrator for  
Hazardous Materials Safety

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(DATE)

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, Department of Transportation, Washington, D.C. 20590. Attention: DHM-31.

Copies of this exemption may be obtained by accessing the Hazardous Materials Safety Homepage at <http://hazmat.dot.gov/exemptions> Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

PO: CWFreeman:dl